

**a. The Boehringer Group's understanding of AWP and intentional manipulation thereof**

251. According to Bedford's own documents, the published AWP for the drugs listed below by the DOJ were, in fact, higher than the actual prices provided to wholesalers. In response to government subpoenas, Bedford produced several price lists setting forth spreads between AWP and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Bedford has consistently offered the above drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. (MDL BV 000799-806).

252. And the size of the spread between the AWP reported to *Red Book* and the wholesale price also evidences AWP manipulation for the following Bedford drugs:

Drug Name	NDC	Quantity	1999 AWP <i>Red Book</i>	W-Sale Spread	%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0612-10	500 mg, 10s	528.00	353.00	201.7%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0612-10	500 mg, 10s	528.00	304.00	135.7%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0612-10	500 mg, 10s	528.00	306.00	137.8%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0613-20	1000 mg, 10s	1,056.00	706.00	201.7%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0613-20	1000 mg, 10s	1,056.00	608.00	135.7%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0613-20	1000 mg, 10s	1,056.00	612.00	137.8%
Acyclovir Sodium (PDI, IJ {S.D.V.})	55390-0613-20	1000 mg, 10s	1,056.00	691.00	189.3%
Amikacin Sulfate (INJ, IJ {S.D.V., P.F.})	55390-0226-02	250 mg/ml, 2 ml 10s	437.50	372.50	573.1%
Amikacin Sulfate (INJ, IJ {S.D.V., P.F.})	55390-0226-02	250 mg/ml, 2 ml 10s	437.50	371.50	562.9%
Amikacin Sulfate (INJ, IJ {S.D.V., P.F.})	55390-0226-04	250 mg/ml, 4 ml 10s	875.00	745.00	573.1%
Amikacin Sulfate (INJ, IJ {S.D.V., P.F.})	55390-0226-04	250 mg/ml, 4ml 10s	875.00	759.00	654.3%
Cytarabine (PDI, IJ {VIAL})	55390-0131-10	100 mg ea	100.28	97.28	3242.7%
Cytarabine (PDI, IJ {VIAL})	55390-0131-10	100 mg ea	6.25	2.95	89.4%
Cytarabine (PDI, IJ {VIAL})	55390-0131-10	100 mg ea	6.25	2.05	48.8%

Drug Name	NDC	Quantity	1999 AWP <i>Red Book</i>	W-Sale Spread	%
Cytarabine (PDI, IJ {VIAL})	55390-0131-10	100 mg ea	6.25	2.65	73.6%
Cytarabine (PDI, IJ {VIAL})	55390-0132-10	500 mg ea	25.00	17.00	212.5%
Cytarabine (PDI, IJ {VIAL})	55390-0132-10	500 mg ea	25.00	17.25	222.6%
Cytarabine (PDI, IJ {VIAL})	55390-0132-10	500 mg ea	25.00	15.00	150.0%
Cytarabine (PDI, IJ {VIAL})	55390-0132-10	500 mg ea	25.00	7.50	42.9%
Cytarabine (PDI, IJ {VIAL})	55390-0133-01	1 gm ea	50.00	33.00	194.1%
Cytarabine (PDI, IJ {VIAL})	55390-0133-01	1 gm ea	50.00	33.50	203.0%
Cytarabine (PDI, IJ {VIAL})	55390-0133-01	1 gm ea	50.00	28.65	134.2%
Cytarabine (PDI, IJ {VIAL})	55390-0133-01	1 gm ea	50.00	15.00	42.9%
Cytarabine (PDI, IJ {VIAL})	55390-0134-01	2 gm ea	98.90	63.95	183.0%
Cytarabine (PDI, IJ {VIAL})	55390-0134-01	2 gm ea	98.90	56.20	131.6%
Cytarabine (PDI, IJ {VIAL})	55390-0134-01	2 gm ea	98.90	28.90	41.3%
Cytarabine (PDI, IJ {VIAL})	55390-0806-10	100 mg ea	6.25	2.75	78.6%
Doxorubicin Hydrochloride (INJ, IJ {M.D.V.})	55390-0238-01	2 mg/ml, 100 ml	945.98	829.98	715.5%
Doxorubicin Hydrochloride (INJ, IJ {M.D.V.})	55390-0238-01	2 mg/ml, 100 ml	945.98	782.48	478.6%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0235-10	2 mg/ml, 5 ml	47.35	36.85	351.0%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0235-10	2 mg/ml, 5 ml	47.35	37.15	364.2%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0236-10	2 mg/ml, 10 ml	94.70	74.70	373.5%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0236-10	2 mg/ml, 10 ml	94.70	74.30	364.2%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0237-01	2 mg/ml, 25 ml	236.74	202.74	596.3%
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0237-01	2 mg/ml, 25 ml	236.74	195.84	478.8%

<b>Drug Name</b>	<b>NDC</b>	<b>Quantity</b>	<b>1999 AWP Red Book</b>	<b>W-Sale Spread</b>	<b>%</b>
Doxorubicin Hydrochloride (INJ, IJ {S.D.V.})	55390-0237-01	2 mg/ml, 25 ml	236.74	197.74	507.0%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0231-10	10 mg	45.07	35.42	367.0%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0231-10	10 mg	45.07	35.37	364.6%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0232-10	20 mg	90.16	72.91	422.7%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0232-10	20 mg	90.16	70.46	357.7%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0233-01	50 mg	225.40	193.40	604.4%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0233-01	50 mg	225.40	186.40	477.9%
Doxorubicin Hydrochloride (PDI, IJ {S.D.V.})	55390-0233-01	50 mg	225.40	188.65	513.3%
Etoposide (INJ, IJ {M.D.V.})	55390-0291-01	20 mg/ml, 5 ml	110.00	103.05	1482.7%
Etoposide (INJ, IJ {M.D.V.})	55390-0291-01	20 mg/ml, 5 ml	110.00	100.05	1005.5%
Etoposide (INJ, IJ {M.D.V.})	55390-0292-01	20 mg/ml, 25 ml	550.00	511.75	1337.9%
Etoposide (INJ, IJ {M.D.V.})	55390-0292-01	20 mg/ml, 25 ml	550.00	498.00	957.7%
Etoposide (INJ, IJ {M.D.V.})	55390-0293-01	20 mg/ml, 50 ml	1,100.00	1,000.10	1001.1%
Etoposide (INJ, IJ {M.D.V.})	55390-0293-01	20 mg/ml, 50 ml	1,100.00	1,025.05	1367.6%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0051-10	50 mg. 10s ea	18.44	15.69	570.5%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0051-10	50 mg. 10s ea	18.44	15.39	504.6%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0051-10	50 mg. 10s ea	18.44	16.19	719.6%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0051-10	50 mg. 10s ea	18.44	15.44	514.7%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0052-10	100 mg 10s ea	35.00	32.05	1086.4%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0052-10	100 mg 10s ea	35.00	31.00	775.0%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0052-10	100 mg 10s ea	35.00	32.00	1066.7%

<b>Drug Name</b>	<b>NDC</b>	<b>Quantity</b>	<b>1999 AWP Red Book</b>	<b>W-Sale Spread</b>	<b>%</b>
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0523-01	200 mg ea	78.00	70.25	906.5%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0523-01	200 mg ea	78.00	68.50	721.1%
Leucovorin Calcium (PDI, IJ {VIAL})	55390-0523-01	200 mg ea	78.00	70.25	906.5%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0031-10	25 mg/ml, 2 ml ea	6.88	4.58	199.1%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0031-10	25 mg/ml, 2 ml ea	6.88	4.18	154.8%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0031-10	25 mg/ml, 2 ml ea	6.88	3.98	137.2%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0032-10	25 mg/ml, 4 ml ea	8.75	5.65	182.3%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0032-10	25 mg/ml, 4 ml ea	8.75	5.15	143.1%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0032-10	25 mg/ml, 4 ml ea	8.75	4.50	105.9%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0033-10	25 mg/ml, 8 ml ea	17.50	13.50	337.5%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0033-10	25 mg/ml, 8 ml ea	17.50	12.20	230.2%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0033-10	25 mg/ml, 8 ml ea	17.50	11.70	201.7%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0034-10	25 mg/ml, 10 ml ea	26.88	21.88	437.6%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0034-10	25 mg/ml, 10 ml ea	26.88	20.38	313.5%
Methotrexate Sodium (INJ, IJ {S.D.V.})	55390-0034-10	25 mg/ml, 10 ml ea	26.88	21.28	380.0%
Mitomycin (PDI, IJ {S.D.V.})	55390-0251-01	5 mg ea	128.05	93.55	271.2%
Mitomycin (PDI, IJ {S.D.V.})	55390-0251-01	5 mg ea	128.05	63.05	97.0%
Mitomycin (PDI, IJ {S.D.V.})	55390-0251-01	5 mg ea	128.05	72.05	128.7%
Mitomycin (PDI, IJ {S.D.V.})	55390-0252-01	20 mg ea	434.60	324.60	295.1%
Mitomycin (PDI, IJ {S.D.V.})	55390-0252-01	20 mg ea	434.60	274.60	171.6%
Mitomycin (PDI, IJ {S.D.V.})	55390-0252-01	20 mg ea	434.60	264.60	155.6%
Vinblastine Sulfate (PDI, IJ {VIAL})	55390-0091-10	10 mg ea	21.25	13.97	191.9%
Vinblastine Sulfate (PDI, IJ {VIAL})	55390-0091-10	10 mg ea	21.25	10.95	106.3%
Vinblastine Sulfate (PDI, IJ {VIAL})	55390-0091-10	10 mg ea	21.25	13.35	169.0%

**b. The Boehringer Group provided other improper incentives**

253. In addition to marketing the spread, The Boehringer Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing “off-invoice” inducements, The Boehringer Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

**c. The Boehringer Group has been the target of multiple government investigations**

254. In connection with its scheme to inflate AWP's, The Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General and the Committee on Commerce of the House of Representatives.

255. In a report published by the DHHS, the DOJ documented at least 32 instances where the published AWP's for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *Red Book*.

Drug	The Boehringer Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.33	\$ 372.17	570%
Mitomycin	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

**5. B. Braun**

256. B. Braun engages in an organization-wide and deliberate scheme to inflate AWP's.

B. Braun has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	dextrose	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
	dextrose in lactated ringers	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
	dextrose w/ sodium chloride	Caloric Agent; Electrolyte Replenisher Used to increase intake of calories and fluids
	heparin sodium (porcine) in d5w	Blood Modifier Used to treat and prevent thrombosis and pulmonary embolism
	sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
	sodium chloride (gu irrigant)	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion

257. The specific drugs manufactured and/or distributed by B. Braun for which relief is currently sought in this case are set forth below or in Appendix A.

258. B. Braun controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, a September 11, 1995 McGaw (acquired by B. Braun in 1997) internal memorandum addresses the company's recognition of its ability to control the published AWP:

Below I have listed all data base companies the specific percentage mark-up that they apply to our "list" prices:

First DataBank	20%
Medispan	25%

Redbook

Whatever we want them to publish

Facts & Comparisons

Information on our products should be submitted to this company although they do not publish pricing, only clinical data

Connie, when we submit our list and AWP prices to these companies this year, let's submit a mark-up of 25% above our list prices to all companies so it will be consistent.

(BBMDL 000013) (Highly Confidential).

259. Notes from an October 1994 telephone conversation between a representative of *Red Book* and McGaw provide further proof that B. Braun understood it could unilaterally control its AWP:

Spoke to Roni Lane at Redbook. She did not know why Baxter is not listed in OTC section. She said we can send her whatever price for AWP we want and she will have it published.[ ] If we increase AWP prices we can send her only AWP to have published ad not list so spread between the 2 won't show. No one regulates pricing this is up to the mfg. Co. and it is option that mfg. Publish theirs, not a requirement.

(BBMDL 013372) (Highly Confidential).

260. B. Braun's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. B. Braun's understanding of AWP and intentional manipulation thereof**

261. Undated notes made in conjunction with a meeting held to address a customer's concerns about B. Braun's decision to increase AWP for a number of drugs reveals B. Braun's understanding of AWP:

Let Rob know that most products are already (AWPs) above wholesaler prices. Make him understand that AWP are based on not what prices they buy it at but at what price they . . . . This doesn't matter as for as setting AWP it is not what the wholesaler sells the products for that set the AWP price (average sell prices).

B. Braun's documents prove that it knew that customers understood AWP's to be related to average wholesale prices. (BBMDL 001907) (Highly Confidential).

262. Braun understood, as reflected in a June 15, 1992 memorandum, that a higher AWP was "advantageous with payors who reimburse based on a cost plus arrangement." (BBMDL 008056) (Highly Confidential).

263. As evidenced by a September 18, 1996 e-mail, B. Braun recognized that manipulating AWP's to meet its competitors was "scandalous," "unethical" and "fraudulent":

I'm writing to you because of a potential problem for McGaw and a potentially larger problem for IVAX. It has to do with the method in which products are sold in our industry at a low actual price, and the wholesaler (our customer) bills Medicare for an arbitrary "average wholesale price." These prices are published in compendia such as Red Book and Blue Book.

I'm wondering if you saw the article in *Barron's* on June 10, 1996. This issue is described in great detail including the fact that the Justice Department is looking into the issue and the Inspector General of Medicare is investigating these practices.

I have held up authorizing the continuation of this practice at McGaw for quite a few months, but they're most anxious to continue the process as our sales are suffering. According to the article, some say that it is not illegal, but it is unethical. I am concerned that McGaw will no sooner increase its average wholesale prices to meet its competitors when the entire industry is going to get slammed for what may be perceived as scandalous, or worse, fraudulent practice of reimbursement.

(BBMDL 000011) (Highly Confidential).

264. Despite discussing and memorializing its concerns, B. Braun promptly proceeded to manipulate its AWP's and market the spread in an effort to match the competition.

265. In an internal memorandum dated December 20, 1996, a B. Braun employee states:

I evaluated each McGaw AWP against Baxter's and Abbott's and individually determined which AWP's should be increased. . . . In general, I raised the McGaw AWP's to make them equivalent to Baxter.

(BBMDL 009658) (Highly Confidential).



266. A second memorandum, created in October of 1997 reveals that B. Braun subsequently performed an analysis to “assure that McGaw AWP’s are in line with Baxter/Abbott AWP’s on competitive products.” (BBMDL 009763) (Highly Confidential). In fact, an October 17, 1997 B. Braun memorandum reveals that the company increased 54 separate AWP’s following a review of 200 drugs to “make them equivalent to both Baxter and Abbott.” (BBMDL 001891) (Highly Confidential). B. Braun increased the AWP’s of 29 drugs in 1996 for the same reason. (BBMDL 009658) (Highly Confidential).

267. In response to government subpoenas, B. Braun produced numerous price lists setting forth spreads between AWP’s and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that B. Braun has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to a particular B. Braun customer.

268. Table 1 is an analysis of certain dosages of B. Braun drugs from a document entitled “PHARMCO.” (BBMDL 011831) (Highly Confidential).

**Table 1**

<b>Drug</b>	<b>Gerimed Unit Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Intralipid	\$6.75	\$57.87	\$51.12	757%
Lactated Ringers 1000	\$1.02	\$11.87	\$10.85	1063%
Travasol	\$6.05	\$82.34	\$76.29	1260%

**b. B. Braun provided other improper incentives**

269. B. Braun, through its employees and agents, also provided free samples of its drugs, and purported educational grants, to providers. The free samples and educational grants would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug.

270. In an October 30, 1998 memorandum addressing pricing strategies for its drug ProcalAmine, in lieu of a price reduction, B. Braun directed personnel to offer customers “something of value instead – for example, give them an educational grant, or sponsor a speaker[.]” The same memorandum also suggests that B. Braun employees might offer a “free case for every so many purchased” to match competitors’ prices “without lowering” the price of its drug. (BBMDL 002088) (Highly Confidential).

**c. B. Braun has been the target of multiple government investigations**

271. In connection with its scheme to inflate AWP, B. Braun has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

272. In a report published by the DHHS (the “DHHS Report”), the DOJ documented at least 23 instances where the published AWP for various dosages of 3 drugs manufactured by B. Braun were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 3 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ’s determination of an accurate AWP for that particular dosage, based upon wholesalers’ price lists, with the AWP reported by B. Braun in the 2001 *Red Book*.

Drug	B. Braun’s 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Dextrose	\$11.28	\$1.61	\$9.67	601%
Dextrose Sodium Chloride	\$11.34	\$1.89	\$9.45	500%
Sodium Chloride	\$11.33	\$1.49	\$9.84	660%

**6. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)**

273. The Fujisawa Group engages in an organization-wide and deliberate scheme to inflate AWP. The Fujisawa Group has stated fraudulent AWP for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Aristocort	triamcinolone, triamcinolone diacetate or triamcinolone acetonide	Anti-Inflammatory, Steroidal; Used in the treatment of asthma
Aristospan	triamcinolone hexacetonide	Anti-Inflammatory Agent, Steroidal Used to provide relief for inflamed areas of the body
Cefizox	ceftizoxime sodium or ceftizoxime in d5w	Antibiotic Agent (Anti-Infective Agent) General antibiotic
Cyclocort	amcinonide	Anti-Inflammatory Agent Used to treat inflammatory symptoms of skin disorders
Lyphocin	vancomycin hydrochloride	Antibacterial Agent Used to treat infections in many different parts of the body
Nebupent	pentamidine isothionate	Antiprotozoal Agent Used to try to prevent Pneumocystis carinii pneumonia
Pentam 300	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
Prograf	tacrolimus	Immunosuppressant Used to lower the body's natural immunity in patients who receive organ transplants
	acyclovir sodium	Antiviral Agent Used to treat herpes simplex infections, varicella-zoster (chickenpox) in people with weakened immune systems, and severe genital herpes infections
	dexamethasone sodium phosphate	Anti-Inflammatory Agent; Antiemetic (Gastrointestinal Agent) Used in various applications to treat inflamed areas of the body
	doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
	fluorouracil	Antineoplastic Used to treat cancer, including colon, rectum, breast, stomach, and pancreas
	gentamicin sulfate	Antibacterial Agent Used to treat serious bacterial infections
	vinblastine sulfate	Antineoplastic Used in the treatment of various forms of cancer, including lymphoma and breast cancer

274. The specific drugs manufactured and/or distributed by The Fujisawa Group for which relief is currently sought in this case are set forth below or in Appendix A.

275. The Fujisawa Group controlled and set the AWP for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, on March 10, 1997, Fujisawa provided MediSpan with an updated listing of pack prices – including AWP – for all of its products. (FJ-MDL 015152-015159).

276. The Fujisawa Group's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. Fujisawa's understanding of AWP and intentional manipulation thereof**

277. Fujisawa understood that providers and intermediaries sought significant AWP spreads. In a March 1995 Monthly Report, dated March 30, 1995, Fujisawa noted:

We have lost our Vanco business at Chartwell. They have recently been handed an edict to order those products with the largest spread between acquisition cost and AWP. Abbott has unbelievably high Vanco AWP. In an effort to counter this loss I suggested we look at picking up the Cefazolin business where our AWP for one gram Cefazolin is over \$8. Unfortunately our 10 gram price does not follow the same formula and is in the \$45 range while Schein is approximately \$58. We do however have a shot at Cefizox for Medicaid/Medicare patients which make up 50% of Chartwell's patients. Medicaid does not reimburse Chartwell for the Rocephin they currently use and while they will not reimburse for Cefizox either they could acquire Cefizox at a fraction of the cost. They use \$400,000 in Rocephin annually, \$200,000 for Medicaid/Medicare patients. That works out to better than \$100K in savings for Chartwell.

(FJ-MDL 005687-88) (Confidential).

278. Fujisawa, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP and marketing practices accordingly. In a May 1995 Monthly Report, dated May 30, 1995, Fujisawa addressed its recent decision to increase its AWP for Vancomycin Hydrochloride and aggressively market the resulting spread increase:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line.

I will settle for the five gram at \$1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 and their contract is \$30 and if our AWP is \$162 we will have to be at least \$29 to have the same spread. Follow?

(FY-MDL 005668-69) (Confidential).

279. In an October 5, 1993 interoffice memorandum discussing Fujisawa's communications with industry pricing compendia, Fujisawa acknowledged that the AWP's for nearly all of its products is inflated at least 33% over direct list prices:

One of the issues regarding our companies AWP listing is that the databases only use our listing as a "Suggested Manufacturers AWP". The standard wholesaler mark-up used by those databases is currently at 25% above direct list price which is our hospital list. Almost all of our products are at 33% or higher above list price.

(FJ-MDL 008346) (Confidential).

280. In response to government subpoenas, Fujisawa produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Fujisawa has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spreads offered to each specific customer here is not practical.

281. Set forth below in Table 1, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa customer price list dated August 24, 1995, and their associated AWP spread. (FJ-MDL 013079-81) (Confidential).

**Table 1**

<b>Drug</b>	<b>Contract Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Triamcinolone	\$14.33	\$17.95	\$3.62	25%
Calcium Gluconate	\$11.50	\$34.00	\$22.50	196%
Cefazolin Sodium	\$139.00	\$367.13	\$228.13	164%
Ceftizoxime Sodium	\$7.50	\$11.86	\$4.36	58%
Amcinonide	\$41.50	\$52.13	\$10.63	26%
Doxycycline Hyclate	\$15.00	\$73.75	\$58.75	392%
Fluphenazine Hydrochloride	\$24.10	\$30.25	\$6.15	25%

<b>Drug</b>	<b>Contract Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Folic Acid	\$7.25	\$11.85	\$4.26	63%
Levothyroxine Sodium	\$3.90	\$38.43	\$34.53	885%
Lidocaine Hydrochloride	\$17.00	\$24.50	\$7.50	44%
Magnesium Sulfate	\$22.00	\$138.25	\$116.25	528%
Mannitol	\$28.00	\$56.50	\$28.50	101%
Neostigmine Methylsulfate	\$8.20	\$89.30	\$81.10	989%
Oxytocin	\$13.50	\$24.50	\$11.00	81%
Potassium Acetate	\$92.00	\$312.40	\$220.40	240%
Potassium Chloride	\$12.25	\$30.50	\$18.25	149%
Potassium Phosphate	\$30.25	\$133.75	\$103.50	342%
Pyridoxine Hydrochloride	\$35.00	\$47.00	\$12.00	34%
Scopolamine Hydrobromide	\$22.00	\$30.00	\$8.00	36%
Selenium	\$18.25	\$195.25	\$177.00	970%

282. Set forth below in Table 2, however, are the AWP, contract prices and spread of a number of drugs (not already referenced above) included in a Fujisawa price list dated November 5, 1996, and their associated AWP spread. (FJ-MDL 008240-53) (Confidential).

**Table 2**

<b>Drug</b>	<b>Wholesaler Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Adenocard IV	\$21.95	\$26.34	\$4.39	20%
Adenoscan	\$179.00	\$223.75	\$44.75	25%
Aristocort A	\$7.05	\$8.46	\$1.41	20%
Atropine Sulfate Injection	\$.64	\$1.12	\$.48	75%
Doxorubicin	\$12.44	\$45.50	\$33.06	266%
Furosemide	\$.74	\$.98	\$.24	32%
Hydroxyzine Hydrochloride	\$.42	\$.65	\$.23	55%
Protamine Sulfate	\$3.33	\$5.32	\$1.99	60%
Selepen	\$18.24	\$29.93	\$11.68	64%
Sodium Acetate	\$8.81	\$14.63	\$5.82	66%
Sodium Bicarbonate	\$2.04	\$3.33	\$1.29	63%
Sodium Chloride	\$.68	\$1.40	\$.72	106%
Sodium Phosphate	\$5.81	\$9.08	\$3.27	56%
Tracelyte	\$8.26	\$11.57	\$3.31	40%
Vinblastine Sulfate	\$26.50	\$43.23	\$16.73	63%
Water for Injection	\$1.10	\$2.34	\$1.24	113%

283. Additional drugs for which Fujisawa manipulated the AWP through false reporting of AWP's is evidenced in part by the following spreads:

Drug Name	NDC	Quantity	1999 AWP <i>Red Book</i>	W- Sale Spread	%
(PENTAMIDINE ISETHIONATE) Nebupent (PDR, IH {S.D.V., P.F.})	57317-0210-06	300 mg ea	98.75	62.75	174.3%
(PENTAMIDINE ISETHIONATE) Nebupent (PDR, IH {S.D.V., P.F.})	63323-0877-15	300 mg ea	98.75	62.75	174.3%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	00469-2210-30	500 mg ea	10.97	3.97	56.7%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	00469-2840-40	1 gm ea	20.35	7.35	56.5%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	00469-2951-00	5 gm ea	136.32	64.82	90.7%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	63323-0284-20	1 gm ea	20.35	7.35	56.5%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	63323-0295-41	5 gm ea	136.32	64.82	90.7%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	63323-0314-61	10 gm ea	272.64	129.64	90.7%
(VANCOMYCIN HYDROCHLORIDE) Lyphocin (PDI, IJ {VIAL})	63323-2210-30	500 mg ea	10.97	3.97	56.7%
Gentamicin Sulfate (INJ, IJ {M.D.V.})	00469-1000-40	40 mg/ml, 20 ml	12.64	7.24	134.1%
Gentamicin Sulfate (INJ, IJ {M.D.V.})	63323-0010-20	40 mg/ml, 20 ml	12.64	9.14	261.1%
Gentamicin Sulfate (INJ, IJ {M.D.V.}, BULK PACKAGE)	00469-1000-60	40 mg/ml, 50 ml	32.59	25.59	365.6%
Gentamicin Sulfate (INJ, IJ {M.D.V.}, BULK PACKAGE)	63323-0010-50	40 mg/ml, 50 ml	32.59	25.59	365.6%

**b. Fujisawa has been the target of multiple government investigations**

284. In connection with its scheme to inflate AWP, Fujisawa has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

285. In a report published by the DHHS (AB-00-86), the DOJ documented at least 35 instances where the published AWP for various dosages of 6 drugs manufactured by Fujisawa were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 6 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Fujisawa in the 2001 *Red Book*.

<b>Drug</b>	<b>The Fujisawa Group's 2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Acyclovir Sodium	\$565.10 <sup>2</sup>	\$371.50	\$193.60	52%
Dexamethasone Sodium Phosphate	\$1.04 <sup>3</sup>	\$.66	\$.38	58%
Fluorouracil	\$2.87	\$1.20	\$1.67	139%
Gentamycin Sulfate	\$12.64 <sup>4</sup>	\$5.40	\$7.24	134%
Pentamidine Isethionate	\$98.75	\$36.00	\$62.75	174%
Vancomycin Hydrochloride	\$10.97 <sup>5</sup>	\$7.00	\$3.97	57%

(P006299-006316).

**7. Immunex**

286. Immunex engages in an organization-wide and deliberate scheme to inflate AWP. Immunex has stated fraudulent AWP for all or almost all of its drugs, including those set forth below.

<sup>2</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>3</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>4</sup> Calculation based on the AWP listed in the 1998 *Red Book*.

<sup>5</sup> Calculation based on the AWP listed in the 1998 *Red Book*.



Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Leukine	sagramostin	Antineutropenic Agent Used to help produce bone marrow and white blood cells
Novantrone	mitoxane hydrochloride	Antineoplastic Used in the treatment of multiple sclerosis and various forms of cancer
Thioplex	lyophilized thiotepa	Antineoplastic Used in the treatment of ovarian and breast cancer, lymphoma and bladder tumors
	leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
	methotrexate sodium	Antineoplastic Used in the treatment of various forms of cancer

287. The specific drugs manufactured and/or distributed by Immunex for which relief is currently sought in this case are set forth below or in Appendix A.

288. Immunex controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, in 2000, in the midst of numerous government investigations concerning AWP manipulation, Immunex denied responsibility for controlling the published AWP for its products. For example, in an October 26, 2000 letter to *Red Book*, Immunex states in pertinent part:

As requested, enclosed please find an updated summary of list pricing and package information for Immunex products. Please note that Immunex Corporation is not responsible for setting the Average Wholesale Price (AWP). Therefore, we do not set or approve AWP information for any Immunex products.

(IAWP023473) (Highly Confidential). Previously, in a 1996 interview, an Immunex spokesperson had informed Barron's that "drug manufacturers have no control over the AWP's published." (IAWP003071) (Hooked on Drugs," *Barron's*, Jun. 10, 1996).

289. Immunex's internal documents, however, establish that it controlled the AWP for all of its products. For example:

a. A January 12, 1996 letter from *Red Book* to Immunex, in pertinent part, states:

This letter is a confirmation letter that we have received and entered your latest AWP price changes in our system.

(IAWP008102) (Highly Confidential).

b. A January 12, 1995 letter from Immunex to *Red Book* states:

Below you will find a list of new suggested Average Wholesale Prices (AWPs) for selected Immunex products, along with a new NDC ... all effective January 10, 1995 ... Please update your databases accordingly. A new copy of Immunex's Average Wholesale Price Product Pricing Guide will be sent to you next week.

(IAWP016500) (Highly Confidential).

290. Immunex's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. Immunex's understanding of AWP and intentional manipulation thereof**

291. Immunex's internal documents reveal that it understood how industry compendia defined and utilized AWPs:

Red Book Definition of AWP

The average wholesale price as we consider it here at Red Book is the price a retail hospital or pharmacy pays if purchases product from wholesaler before the discount if any.

Blue Book Definition of AWP

AWP represents an average price which a wholesaler would charge a pharmacy for a particular product.

(IAWP002238) (Highly Confidential).

292. In an internal document entitled "Health Care Policy Fast Facts," created in 1995, Immunex urged its sales personnel to remember "[p]hysician's offices use their own charge schedule for billing purposes, and get reimbursed at AWP, based on the published prices in the pricing databases." (IAWP012961) (Highly Confidential).

293. Recently, in a January 3, 2000 interoffice memo, Immunex discussed the significant revenues to be made by providers which used its Leucovorin and Methotrexate products. Specifically, Immunex stated that, "Leucovorin and Methotrexate represent significant revenue sources for the physician office or clinic. Due to the 'spread' (difference between acquisition cost and AWP), physicians have reaped substantial profits." (IAWP051149-52) (Highly Confidential).

294. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP's and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:

Here's the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is \$117.79 and \$221.71. **However**, payors take the \$117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to \$23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is \$235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable (\$188.48). So here's what the spread looks like:

\$235.60 (AWP)	\$188.48
	(80% Medicare allowable)
-\$112.06 (AOR contract price)	-\$112.06
+\$123.54 per 500 mcg vial	\$76.42 (68% spread)
(110% spread)	

(IAWP008528) (Highly Confidential) (emphasis in original).

295. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a "Reimbursement Hotline" for a number of its products (IAWP016686-88) (Highly Confidential).

296. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the

spread was of great importance to its customers. The following is an example of phony AWP's and the spread created for Immunex drugs:

Drug Name	NDC	Quantity	1999 AWP <i>Red Book</i>	W-Sale Spread	%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-12	25 mg/ml, 8 ml	16.73	11.73	234.6%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-12	25 mg/ml, 8 ml	16.73	9.88	144.2%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-12	25 mg/ml, 8 ml	16.73	10.23	157.4%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-15	25 mg/ml, 2 ml	4.75	2.75	137.5%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-15	25 mg/ml, 2 ml	4.75	1.00	26.7%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-15	25 mg/ml, 2 ml	4.75	2.35	97.9%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-15	25 mg/ml, 2 ml	4.75	1.25	35.7%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-16	25 mg/ml, 10 ml	20.48	15.48	309.6%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-16	25 mg/ml, 10 ml	20.48	13.33	186.4%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-16	25 mg/ml, 10 ml	20.48	10.98	115.6%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-16	25 mg/ml, 10 ml	20.48	13.73	203.4%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-18	25 mg/ml, 4 ml	8.50	3.60	73.5%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-18	25 mg/ml, 4 ml	8.50	4.48	111.4%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-18	25 mg/ml, 4 ml	8.50	3.65	75.3%
(METHOTREXATE SODIUM) LPF (INJ, IJ {S.D.V., P.F.})	58406-0683-18	25 mg/ml, 4 ml	8.50	5.00	142.9%
Methotrexate Sodium (INJ, IJ {S.D.V., P.F.})	58406-0671-05	1 gm ea	61.44	22.24	56.7%

<b>Drug Name</b>	<b>NDC</b>	<b>Quantity</b>	<b>1999 AWP <i>Red Book</i></b>	<b>W-Sale Spread</b>	<b>%</b>
Methotrexate Sodium (INJ, IJ {S.D.V.})	58406-0671-05	1 gm ea	61.44	11.89	24.0%
Methotrexate Sodium (INJ, IJ {S.D.V.})	58406-0671-05	1 gm ea	61.44	12.29	25.0%
Methotrexate Sodium (INJ, IJ {VIAL, L.P.P.})	58406-0681-14	25 mg/ml, 2 ml	4.75	1.75	58.3%
Methotrexate Sodium (INJ, IJ {VIAL, L.P.P.})	58406-0681-14	25 mg/ml, 2 ml	4.75	1.15	31.9%
Leucovorin Calcium (PDI, IJ {P.F.})	58406-0623-07	350 mg ea	137.94	118.94	626.0%
Leucovorin Calcium (PDI, IJ {P.F.})	58406-0623-07	350 mg ea	137.94	125.69	1026.0%
Leucovorin Calcium (PDI, IJ {P.F.})	58406-0623-07	350 mg ea	137.94	125.44	1003.5%

**b. Immunex provided other improper incentives**

297. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential). The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug.

**c. Immunex has been the target of multiple government investigations**

298. In connection with its scheme to inflate AWP's, Immunex has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, and the Attorney General for the State of California.

299. In a report published by the DHHS (the "DHHS Report"), the DOJ documented at least 7 instances where the published AWP's for various dosages of 2 drugs manufactured by Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that

particular dosage, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

<b>Drug</b>	<b>2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

300. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale price was \$142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

**d. Immunex Concealed Its AWP Manipulation**

301. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of "simplifying" its product listings, on June 3, 1994, Immunex instructed the *Red Book* to "delete all references to Direct Price for all Immunex products, effective immediately" and confirmed that "only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]" (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from the State.

**8. The Johnson & Johnson Group (J&J, Centocor and Ortho)**

302. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Johnson & Johnson Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Aciphex	rabeprazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections
Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
Pancrease	amylase-lipase-protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal disorders
Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV-infected, cancer or chronic renal failure patients

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Regranex	becaplermin	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type
Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
Retin-A	tretinoin	Antiacne Agent Used to treat acne
Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone
Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
Tylenol with codeine		
Ultracet	tramadol- acetaminophen	Analgesic Used to relieve pain
Ultram	tramadol hcl	Analgesic Used for management of pain
Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
Vascor	bepiridil hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension



303. The specific drugs manufactured and/or distributed by The Johnson & Johnson Group for which relief is currently sought in this case are set forth below or in Appendix A and in this section below.

304. The Johnson & Johnson Group controlled and set the AWP for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia.

305. The Johnson & Johnson Group's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. The Johnson & Johnson Group's understanding of AWP and intentional manipulation thereof**

306. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWP. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First DataBank or the Red Book." (J&J000599) (Highly Confidential).

307. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWP and to market the spread to increase the sales of its products.

308. For example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

309. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that, "[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice." Moreover, the "Financial Analysis" section of the guide includes a "REMICADE® (infliximab) Financial Impact Worksheet," which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

310. Set forth below in Table 1 are the contract prices (not already referenced above) included in a J&J contract price list (effective from April 1, 1997 through March 31, 1998) contained in a supply agreement with Managed Healthcare Associates, Inc. dated March 17, 1997 and the AWP published in the 1997 *Red Book*, and their associated AWP spread. (J&J000121-23) (Highly Confidential).

**Table 1**

Drug	Contract Price	AWP	\$ Diff AWP	% Spread
Procrit (epoetin alfa)	\$950.00 (4000 u/ml 25x1 ml vials)	\$1200	\$250	20.8%
Ultram (tramadol hcl)	\$53.97 (1x100 50 mg)	\$62.34	\$8.37	13.4%
Duragesic fentanyl transdermal)	\$44.94 (25M 25mcg/hr 1x5)	\$53.94	\$9	16.7%
Floxin (ofloxacin)	\$276.89 (1x100 btls 200 mg/case)	\$332.28	\$55.39	16.7%
Propulsid (cisapride)	\$56.62 (10mgx100)	\$67.96	\$11.34	16.7%
Risperdal (risperidone)	\$335.59 (3 mg 1x100)	\$402.72	\$67.13	16.7%
Topamax tiramate)	\$123.00 (100 mg 1x60)	\$147.60	\$24.6	16.7%

311. Additional evidence of the phony nature of this defendant's AWP's arises from its manipulation of its reported AWP's in late 2000 and 2001, when it increased its reported AWP's for certain of the drugs identified in Appendix A across the board without any change in product or service offered. If these AWP's were real, price increases would not be uniform and would bear a relationship to some product change. At the same time of these price increases, cost to

providers did not increase, further evidencing the phony nature of the AWP. The specific drugs subject to this manipulation were Aciphex, Bicitra, Concerta, Ditropan XL, Duragesic, Ehmiron, Erycette, Flexeril, Floxin, Grifulvin V, Haldol, Levaquin, Monistat-Derm, Mycelex, Neutraphos, Pancrease, Parafon Forte DSC, Polycitra, Regranex, Reminyl, Renova, Retin-A Micro, Risperdal, Spectrazole, Sporanox, Terazol, Tolectin, Topamax, Tylenol with Codeine, Tylox, Ultracet, Ultram, Vascor and Vermox.

**b. The Johnson & Johnson Group provided other improper incentives**

312. In addition to marketing the spread, The Johnson & Johnson Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing “off-invoice” inducements, The Johnson & Johnson Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

**c. The Johnson & Johnson Group has been the target of multiple government investigations**

313. In connection with its scheme to inflate AWP, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

314. In a report published by the GAO, federal investigations have documented fraudulently inflated AWP reported for epoetin alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.<sup>6</sup>

315. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen’s

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<sup>6</sup> Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

AWP scheme, as well as the inflated cost to the State, are even more outrageous given the fact that the research and development of epoetin alpha was originally underwritten by grants from the federal government.<sup>7</sup>

**d. J&J Concealed Its AWP Manipulation**

316. The Johnson & Johnson Group deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).

**9. Novartis**

317. Novartis engages in an organization-wide and deliberate scheme to inflate AWP's. Novartis has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Clozaril	clozapine	Antipsychotic (Psychotherapeutic Agent) Used to treat schizophrenia
Combipatch	estradiol & norethindrone acetate	Hormone Used to treat symptoms of menopause
Comtan	entacapone	Antidyskinetic Agent Used in combination with levodopa/carbidopa to treat Parkinson's
Estraderm	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
Exelon	rivastigmine tartrate	Cholinesterase Inhibitor (Central Nervous System Agent) Used to treat the symptoms of mild to moderate Alzheimer's disease
Femara	letrozole	Antineoplastic Used to treat certain types of breast cancer in women
Lamisil	terbinafine hcl	Antifungal Agent Used to treat fungus infections of the scalp, body, groin, feet, fingernails, and toenails

<sup>7</sup> Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Lamprene	clofazimine	Antibacterial Agent Used to treat leprosy
Lescol	fluvastatin sodium	HMG-CoA Reductase Inhibitor (Cardiovascular Agent) Used to lower levels of cholesterol and other fats in the blood
Lotensin	benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
Lotensin HCT	benazepril & hctz	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
Lotrel	amlodipine besylate- benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
Miacalcin	calcitonin (salmon)	Calcitonin (Hormone) Used to treat Paget's disease of bone. Also used to prevent continuing bone loss in women with postmenopausal osteoporosis and to treat hypercalcemia
Parlodel	bromocriptine mesylate	Antidyskinetic Agent; Antihyperprolactinemic; Growth Hormone Suppressant Used to treat certain menstrual problems or to stop milk production. Also used to treat infertility and Parkinson's disease
Ritalin	methylphenidate hcl	Central Nervous System Stimulant Used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy
Starlix	nateglinide	Antidiabetic Agent Used to treat a type of diabetes mellitus (sugar diabetes) called type 2 diabetes
Tegretol	carbamazepine	Anticonvulsant; Antipsychotic (Psychotherapeutic Agent) Used to control some types of seizures in the treatment of epilepsy
Trileptal	oxcarbazepine	Central Nervous System Agent; Anticonvulsant Used in the treatment of partial seizures
Vivelle	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
Vivelle-DOT	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

318. The specific drugs manufactured and/or distributed by Novartis for which relief is currently sought in this case are set forth below or in Appendix A.

319. Novartis controlled and set the AWP's for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia.

320. Novartis's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

**a. Novartis's understanding of AWP and intentional manipulation thereof**

321. Novartis has engaged in an ongoing deliberate scheme to inflate AWP and to market the spread to increase the sales of its products.

322. Additional evidence of the phony nature of this defendant's AWP arises from its manipulation of its reported AWP in late 2000 and 2001, when it increased its reported AWP for certain of the drugs identified in Appendix A across the board without any change in product or service offered. If these AWP were real, price increases would not be uniform and would bear a relationship to some product change. At the same time of these price increases, cost to providers did not increase, further evidencing the phony nature of the AWP. The specific drugs subject to this manipulation were Clozaril, CombiPatch, Comtan, Diovan, Diovan HCT, Elidel, Estraderm, Exelon, Famvir, Femara, Focalin, Lamisil, Lescol/Lescol XL, Lotensin, Lotensin HCT, Miacalcin Injection & Nasal Spray, Parlodel, Rescula, Ritalin Hydrochloride, Ritalin LA, Starlix, Tegretol, Tegretol-XR, Trileptal, Vivelle/Vivelle-Dot, Voltaren Ophthalmic, Zaditor, and Zelnorm.

**b. Novartis provided other improper incentives**

323. In addition to marketing the spread, Novartis has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Novartis provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

**c. Novartis has been the target of government investigations**

324. In connection with its scheme to inflate AWP, Novartis has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of